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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/807,965 | 03/24/2004 | Dietrich Gravenstein | UF-168C2DC1 | 4096 |
| 23557 | 7590 | 02/27/2006 | EXAMINER | |
| SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950 | | | LEUBECKER, JOHN P | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3739 | |

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | | | |
|------------------------------|-------------------|--------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/807,965 | GRAVENSTEIN ET AL. | |
| | Examiner | Art Unit | |
| | John P. Leubecker | 3739 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 24 March 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-17 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-17 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>3/24/04 & 8/19/05</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

Specification

1. The abstract of the disclosure is objected to because it should not begin with "Disclosed is" and should not contain claim phraseology. Correction is required. See MPEP § 608.01(b).

2. The disclosure is objected to because of the following informalities: the continuation data in the first paragraph of the specification should be updated.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Fritch et al. (U.S. Pat. 4,607,622).

Fritch et al. discloses an imaging stylet comprising a malleable stylet (either at col.7, lines 48-50 or col.8, lines 28-31), a flexible image guide (62), means for viewing an image (52,54), at least one flexible illumination fiber (64), and a removable sheath (60). The distal ends of the stylet, image guide and illumination fiber are all co-extensive (note Figure 6 and not

that either channel 66 or the sheath itself, both of which can accommodate the stylet as pointed out above, are co-extensive with the optical fibers). Further as to claim 2, the sheath is adapted to isolate the distal end of the image guide (col.7, lines 63-64) and comprises a transparent end portion (70, Fig.6). It is noted that the language in claims 1 and 6 directed to the use of the imaging stylet with a tube is related to its intended use and given no structural weight.

5. Claims 11-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Reid, Jr. (U.S. Pat. 4,800,870).

Reid, Jr. discloses a malleable stylet (6,7) and a flexible image guide (16), both having proximal and distal ends and being disengagably connected to each other along at least most of their length (note stylet channel 5, col.3, lines 13-36), the latter attributing to a center of balance located in approximately center 1/3 portion along the longitudinal axis between the proximal and distal ends. In addition, the Examiner takes the position that this particular center of balance would be inherent due to the nature of the symmetric structure of the combination between the proximal and distal ends (i.e., the structure of the combination of the image guide and stylet is substantially a mirror image between the center and the distal end and the center and the proximal end). As to claim 12, the malleable stylet is disposed within a sheath (6) having formed therein a channel (channel accommodating image guide 16, shown in Figure 2) extending longitudinally substantially parallel to the stylet. As to claims 13 and 14, the above mentioned channel can be considered as O-shaped which encompasses a C-shape and a U shape. As to claims 15 and 16, since the stylet channel holds the image guide (16) in a certain relationship to the cross-sectional area of the stylet (e.g., off-center) as in Figure 2 or since the channel arranges

both in a longitudinal relationship, they can be considered as "indexed". As to claim 17, the image guide (16) and sheath (6) can be considered a scope, and further includes a flexible illumination fiber (3) running substantially coextensive with the length of the imaging guide, wherein the scope includes a channel (5) running substantially parallel to the longitudinal axis of the image guide.

6. Claims 11-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Hori et al. (U.S. Pat. 5,941,818).

Hori et al. discloses a malleable stylet (64,70 Figs.1 and 5) and a flexible image guide (40), both having proximal and distal ends and being disengagably connected to each other along at least most of their length (col.5, lines 12-21), the latter attributing to a center of balance located in approximately center 1/3 portion along the longitudinal axis between the proximal and distal ends. In addition, the Examiner takes the position that this particular center of balance would be inherent due to the nature of the symmetric structure of the combination between the proximal and distal ends (i.e., the structure of the combination of the image guide and stylet is substantially a mirror image between the center and the distal end and the center and the proximal end). As to claim 12, the malleable stylet includes a malleable rod (70) within a sheath (64), the sheath having formed therein a channel (68,Fig.5) extending longitudinally substantially parallel to the stylet. As to claims 13 and 14, the channel is U-shaped as shown in Figure 5 or C-shaped if rotated 90 degrees. As to claims 15 and 16, since the stylet channel holds the image guide (40) in a certain relationship to the cross-sectional area of the stylet (e.g., off-center) as in Figure 5 or since the channel tightly grips the image guide (col.5, line 20) to arrange both in a

longitudinal relationship, they can be considered as "indexed".

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 4, 5, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fritch in view of Suzuki et al. (U.S. Pat. 5,127,079).

Fritch et al. fail to explicitly mention the material used to make the image guide.

Assuming glass optical fibers in the Fritch et al. device, the skilled artisan in the optical fiber art would recognize the obvious alternative use of glass and plastic fibers. Suzuki et al. is just one reference that teaches use of plastic optical fibers for imaging in an endoscope. Suzuki et al. also teaches motivation to use plastic optical fibers instead of glass ones: glass optical fibers are costly, relatively rigid, easily broken and difficult to pass through curved or bent arteries (col.1, lines 23-25). Therefore, it would have been obvious to one of mere ordinary skill in the art to have provided a plastic image guide in the Fritch et al. device since, when reducing such device to practice, one would have to chose from materials known in the art at the time the invention was made and plastic optical fibers, in view of Suzuki et al., clearly have desirable advantages.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Nakao (US 2005/0085694)

Christopher (U.S. Pat. 6,849,042)

Aydelotte (U.S. Pat. 6,629,924)

Crawford (U.S. Pat. 5,944,654)

Silverstein et al. (U.S. Pat. 5,025,778)

Takahashi (U.S. Pat. 4,616,631)

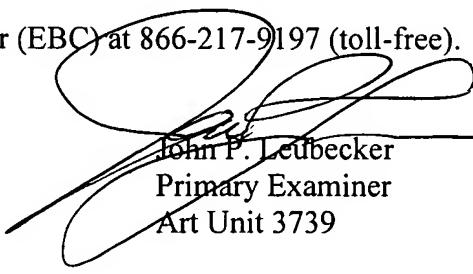
Silverstein et al. (U.S. Pat. 4,646,722)

Adair (U.S. Pat. 5,489,256)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (571) 272-4769. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


John P. Leubecker
Primary Examiner
Art Unit 3739